REMARKS/ARGUMENTS

The Office Action mailed March 18, 2005, has been received and reviewed. Claims 1 through 12 are currently pending in the application. Claims 1 through 12 stand rejected. Applicants respectfully request reconsideration of the application.

Double Patenting Rejection Based on U.S. Patent No. 6,627,197

Claims 1 through 12 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 through 15 of U.S. Patent No. 6,627,197. In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the terminal disclaimer should not be construed as acquiescence in the Examiner's double patenting or obviousness-type double patenting rejections. Attached are the terminal disclaimer and accompanying fee.

35 U.S.C. § 112 Claim Rejections

Claims 1 through 3 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

A "patent specification is not intended nor required to be a production specification" (MPEP § 608.01(h)). "Furthermore, a patent need not teach, and preferably omits, what is well known in the art" *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) (*citing Lindemann Maschinenfabrik v. American Hoist and Derrick,* 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984)).

The Office asserts that "there is no teaching in the art or specification as to how this [the N-X-A or A-X-N] compound will treat HIV because there is no indication that it can specifically target virus or infected cells" (page 5 of the Office Action). Applicants note that the claim language itself recites how the compound targets infected cells. Specifically, the claims recite

that "X is a peptide susceptible to digestion by a human immunodeficiency virus [HIV] protease" and "A is a protein synthesis inactivating protein that is inactive until X is digested." Hence, the person of ordinary skill in the art understands that an HIV infected cell will express the HIV protease, which will cleave X and activate A. Thus, only cells infected with an HIV express the protease that activates the protein synthesis inhibition activity of the claimed compound. For example, see working Example 8 (para. 77) of the specification, where cleavage by HIV protease activates the claimed compound and kills the host cells.

Furthermore, the modes of viral transmission (by any mechanism), the ability of the virus to be shielded by the blood brain barrier and the complexity and variations of the disease are irrelevant, since no matter how the virus enters the cell, expression of the HIV protease allows the claimed compound to be activated, thereby treating HIV infection.

Moreover, the specification contains extensive discussion of mechanisms for targeting a cell and moving the compound into the cell. For example, the specification describes attaching a hydrophobic moiety to the compound to allow the compound to enter cells *in vivo* (*see*, *e.g.*, para. 47, 66 of the specification), attachment of targeting moieties are also described (*see*, *e.g.*, paras. 40, 49, 50, 67, and 73 of the specification). Hence, the specification provides guidance as to how one would use the claimed compositions N-X-A or A-X-N for treating HIV and provides a working example of the compounds in the presence of the HIV protease (*see*, Example 8, using yeast cells expressing the HIV protease). Therefore, the specification provides ample guidance and enables a person of ordinary skill in the art to make and use the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection, as hereinafter set forth.

Functional equivalents of the adenine moiety, as recited in claim 1, are discussed in the specification, for example, in paragraph 62. The specification describes the function of the adenine moiety as occupying the active site of the protein synthesis inactivating protein "A", *e.g.*, ricin A chain, to inhibit the protein until such time as "X" is cleaved. Pteroic acid is one "functional equivalent" (*see*, paragraph 62 of the specification). Hence, the specification

describes the function and provides a representative example of the "functional equivalents" known in the art.

Since the specification teaches the function of the adenine moiety and "functional equivalents" are known in the art, the phrase would reasonably appraise the person of ordinary skill in the art of the metes and bounds of the claim. Therefore, the phrase should not be rejected as vague or indefinite. Reconsideration and withdrawal of the rejection are respectfully requested.

35 U.S.C. § 102 Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 6,333,303 to Borgford

Claims 1 through 12 stand rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Borgford (U.S. Patent No. 6,333,303). Applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Borgford reference is not prior art under 35 U.S.C. §§ 102(a), since the Borgford patent did not issue until December 25, 2001. The present application is a divisional of a U.S. application filed June 15, 2001, prior to Borgford, and claims priority to U.S. Provisional Application No. 60/182,759, filed February 16, 2000. Therefore, U.S. Patent 6,333,303 is not prior art under 35 U.S.C. § 102(a).

Moreover, Borgford does not teach each and every element as set forth in the claim. For example, Borford does not teach the use of a lectin and/or hydrophobic agent as recited in the claims. Since Borgford does not teach each and every element of the claims, the reference does not anticipate the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Anticipation Rejection Based on PCT Patent Application Publication No. WO 97/41233 to Borgford

Claims 1 through 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Borgford (PCT Patent Application Publication No. WO 97/41233). Applicants respectfully traverse this rejection, as hereinafter set forth.

International Patent Publication WO 97/41233 is the same disclosure present in U.S. Patent 6,333,303. Therefore, the same reasoning presented for the previous rejection applies to this rejection. Since the reference does not teach each and every element of the claims, the reference does not anticipate the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

Claims 1-12 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

Stephen R. Christian
Registration No. 32,687
Attorney for Applicants
P.O. Box 1625
Idaho Falls, ID 83415 – 3899
Phone: 208-526-9140
Fax: 208-526-8339

Date: 16 JUNE 2005